

AnoviumTM *Solution*



Clean. Pure. Natural.

NEXUSTM
CMF

**A new therapy for patients
suffering the pain and reduced
function of Temporomandibular
Joint Disease.**

Amniotic Fluid Allograft Standards

Use of amniotic fluid allografts is not regulated by the FDA as a drug; rather, amniotic fluid is categorized as “human cells, tissues and cellular tissue-based product (HCT/P).”¹

HCT/Ps are defined in 21 CFR 1271.2(d) as articles containing or consisting of human cells or tissues that are intended for implementation, infusion or transfer into a human recipient¹.

Amniotic Fluid is regulated under section 361 of the public Health Service Act and 21 CFR Part 1271 by meeting the following criteria (21 CFR 1271.10[a]):

- 1 The HCT/P is minimally manipulated**
- 2 The HCT/P is intended for homologous use only**
- 3 The manufacturer of the HCT/P does not combine the cells or tissues with another article other than water, crystalloids or the sterilizing, preserving, or storage agent**
- 4 The HCT/P does not have a systemic effect**

A tissue donor is selected based on medical and social history which meets the Standards of the American Association of Tissue Banks (AATB)², United States Public Health Service (USPHS)³, and the FDA¹.

Anovium Solution™ is prepared from full-term Cesarean Section birth tissues which were voluntarily donated. The donors are tested and found negative for a wide range of communicable diseases.

1. U.S. Food and Drug Administration. Minimal manipulation of human cells, tissues, and cellular and tissue-based products: draft guidance, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm427692.htm>.

2. Standards for Tissue Banking: Arlington, VA American Association of Tissue Banks (AATB), latest edition

3. United States Public Health Service

Setting a Higher Standard for Collection, Sterilization, and Purification

Anovium Solution™ is the only amniotic fluid allograft governed by:

FACT Accreditation

FACT accreditation is the threshold for excellence in cellular therapy. FACT-accredited organizations voluntarily seek and maintain FACT accreditation through a rigorous process, demonstrating their belief that patient needs are paramount. Receiving care from a cellular therapy organization within the prestigious community of FACT-accredited organizations can make you confident that you are in good hands.⁴

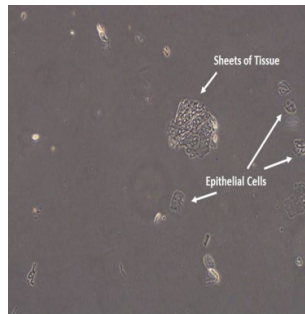
Protocol Approved by Institutional Review Board Standards⁵

Microscopic observation of product “cleanliness”⁶

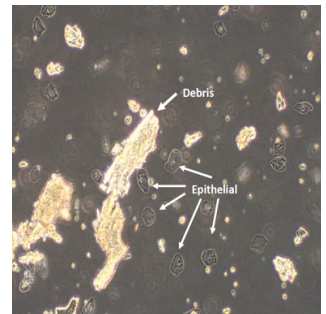
Clean.



Anovium Solution™



Product A



Product B

4. www.FACTwebsite.org - Foundation for the Accreditation of Cellular Therapy

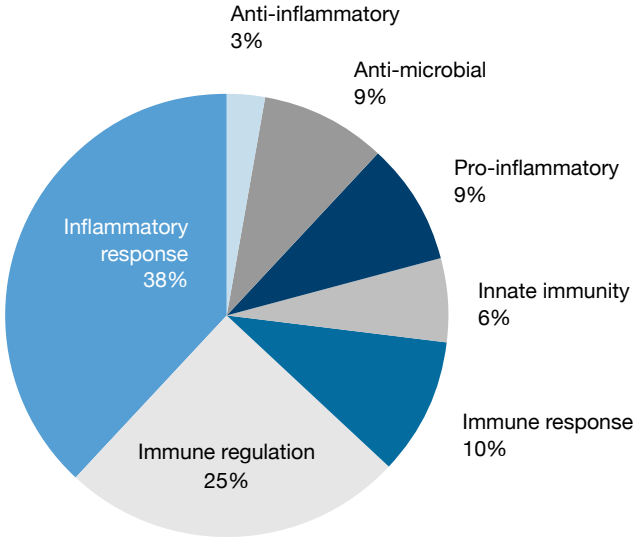
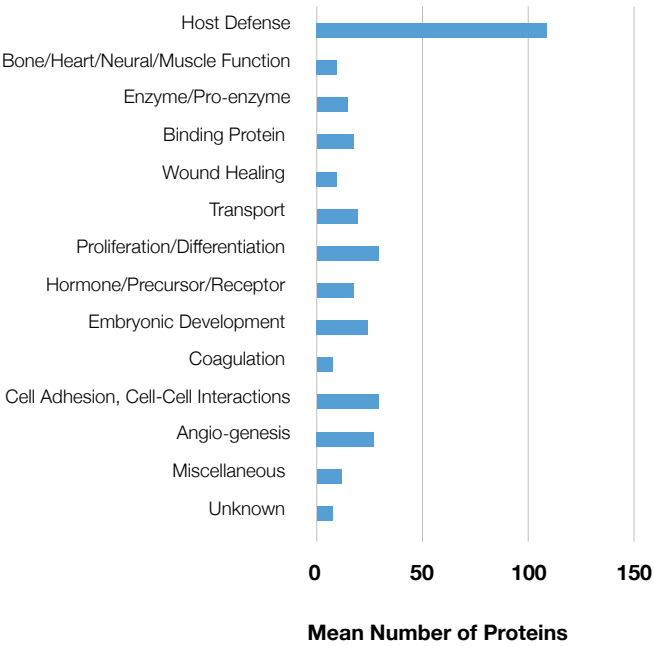
5. Pierce, J. Collection and characterization of amniotic fluid from scheduled C-section deliveries. Cell Tissue Bank. DOI 10.1007/s10561-016-9572-7

6. Internal Data

Pure.

Confidence and Trust in Anovium Solution™ because reporting comes from Published Data⁵.

- On Average, 304 +/- 20 Cytokines in 1mL
- Approximately 90% of the proteins are present in each 1mL sample
- Anovium Solution™ is angiogenic
- Protein arrays show Anovium Solution™ rich in Cytokines with **anti-microbial, immuno-modulatory, and growth-promoting** activities:



5. Pierce, J., Collection and characterization of amniotic fluid from scheduled C-section deliveries. Cell Tissue Bank. DOI 10.1007/s10561-016-9572-7

Natural.

Anti-microbial, Immuno-modulatory, Growth-Promoting

Anovium Solution™ is a new therapeutic form of medical management to help patients suffering the pain and reduced function of temporomandibular disease.



- Stored at -20 Degree Celsius
- Allow 5-10 minutes to thaw before injection
- Inject 1mL into superior joint space of TMJ

**For more information,
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Your Partner in Innovation

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